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Developing Injectable Medicines

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January 20, 2006

VIA FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Citizen Petition Requesting that FDA Should Not Approve Abbreviated New Drug Applications ("ANDAs") for Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension Products Unless Certain Conditions Are Met

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted pursuant to 21 CFR §10.30, requesting that the Commissioner of the Food and Drug Administration refrain from approving any Abbreviated New Drug Application ("ANDA") application for any generic version or other pharmaceutical alternative of Celestone® Soluspan® (brand of betamethasone sodium phosphate and betamethasone acetate Injectable Suspension, USP) unless and until any such applicant satisfies the condition set forth in this Petition.

A. Action Requested

The petitioner respectfully requests that the Commissioner of the Food and Drug Administration refrain from approving as an ANDA any product referencing

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Celestone® Soluspan® unless and until the ANDA applicant demonstrates bioequivalence to the Reference Listed Drug ("RLD"), Celestone® Soluspan®, the subject of New Drug Application ("NDA") 14-602.

B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act ("the FFDCA") requires that any person filing an ANDA for a generic equivalent of a RLD demonstrates that the new drug is bioequivalent to the approved RLD [Section 505(j)(2)(A)].

The *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the List" / "Orange Book" / "Electronic Orange Book"), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("the FDA") under the FFDCA. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

The RLD, Celestone® Soluspan® (brand of betamethasone sodium phosphate and betamethasone acetate Injectable Suspension, USP), is listed in the current edition of the Electronic Orange Book in the 'active' Drug Product List section (Attachment A). Although listed in this section, the drug product has been under a limited distribution

program due to concerns related to the manufacturer, Schering-Plough Corporation. Based upon limited availability and manufacturing issues at Schering-Plough, which resulted in a Consent Decree ordered in May 2002, a request for determination that the product was not shortened from distribution and sale for safety or effectiveness reasons was submitted to the FDA. This request was made under 21 CFR 10.30 in a Citizen Petition dated September 3, 2004 submitted by Hikma Farmaceutica (Portugal) LDA.

On January 12, 2006, a Federal Register notice was published indicating that the product was not withdrawn from sale for safety or effectiveness reasons [Federal Register: January 12, 2006 (Volume 71, Number 8)]. Within the notice, reference is made to the limited availability of the product for use as an RLD in an ANDA filing. It is stated that "if the RLD product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product."

Schering-Plough Corporation issued a press release on January 3, 2006 announcing completion of their cGMP Work Plan and Validation Certification Program under the FDA Consent Decree (Attachment B). As a result of this public notification, Schering-Plough Corporation was contacted by the Petitioner as to the availability of the Celestone® Soluspan® drug product. A representative of Kenilworth

Pharmaceuticals, the division of Schering-Plough responsible for the manufacture of Celestone® Soluspan®, has indicated that the restricted distribution of this product has ended and increased quantities of product will be available for distribution (Attachment C).

Based on the stated information, the petitioner requests that the Commissioner of the Food and Drug Administration not approve as an ANDA any product referencing Celestone® Soluspan® unless and until the ANDA applicant demonstrates bioequivalence to the Reference Listed Drug ("RLD"), Celestone® Soluspan®.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Everett Carmody
President
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Attachments:

Attachment A:	Page 3 – 46 of 351 of the 25th Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations
Attachment B:	Schering-Plough News Release, reprinted from website: http://www.sgp.com/schering_plough/
Attachment C:	Transcript of telephone discussion with representative of Kenilworth Pharmaceuticals, a division of Schering-Plough Corporation